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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,300	05/08/2007	David I. Yule	21108.0042U2	1912
23859 7590 06/27/2008 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER PAK, MICHAEL D	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 06/27/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,300	<b>Applicant(s)</b> YULE ET AL.	
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-89 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I in the reply filed on March 10-2008 is acknowledged.

However, applicant's response is partly non-responsive by electing the mutant of claim 28. Mutant of claim 28 appears to be a multiple mutant subgeneric claim with several mutants and a single mutant must be elected. The election of the mutant is a separate restriction requirement and not a species requirement.

Furthermore, examiner requests a clarification of each of the SEQ ID NO: claimed and mutational structural relationship between the different SEQ ID NO:.

2. The previous restriction is recast below for applicant's convenience.

This Application is a 371 of PCT/US05/02380, filed January 26, 2005, which claims priority to US Provisional Application 60/539,245, filed January 26, 2004.

Claim 1-89 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-52, 59-61, 76-85, drawn to an inositol 1, 4, 5-triphosphate receptor (InsP3R) mutant.

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Group 2, claim(s) 53-58, 62-67, drawn to a nucleic acid encoding a mutant inositol 1, 4, 5-triphosphate receptor (InsP3R) mutant, a vector comprising a nucleic acid sequence encoding a mutant InsP3R, a cell comprising the vector comprising a nucleic acid sequence encoding a mutant InsP3R.

Group 3, claim(s) 68-72, drawn to a method of screening for an agent that preferentially modulates calcium release phosphorylated InsP3R.

Group 4, claim(s) 73, drawn to a method of expressing a mutant InsP3R in a cell *in vivo*.

Group 5, claim(s) 74, drawn to a method of treating a subject who has xerostomia, comprising introducing into the subject an expression vector comprising a nucleic acid sequence encoding a mutant InsP3R.

Group 6, claim(s) 75, drawn to a method of treating a subject who has cystic fibrosis, comprising introducing into the subject an expression vector comprising a nucleic acid sequence encoding a mutant InsP3R.

Group 7, claim(s) 86, 87, drawn to a method of inhibiting apoptosis in a transplant in a subject comprising introducing a vector comprising a nucleic acid sequence encoding a mutant InsP3R.

Group 8, claim(s) 88, drawn to a method of treating a subject with HIV, comprising introducing a vector comprising a nucleic acid sequence encoding a mutant InsP3R.

Group 9, claim(s) 89, drawn to a method of treating a subject with arthritis comprising introducing a vector comprising a nucleic acid sequence encoding a mutant InsP3R.

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature, amino acid substitutions in InsP3 protein, was known at the time of filing. Thus, the groups do not share a special technical feature because at the time of filing, Mikoshiba, 1997, Current Opinion in Neurobiology, 7: 339-

345 teaches that single amino acid substitution studies on InsP3R proteins were known (Mikoshiba, page 339, under “InsP3-binding core in the ligand-binding domain”).

Groups 1-9 are similar to each other as they are drawn to InsP3R protein with various amino acid substitutions, nucleic acid sequences that encode them, methods of using cells comprising a nucleic acid expression vector that expresses Insp3R mutants in screens for compounds that modulate them, and to methods of using the nucleic acid encoding InsP3R mutants in treatments.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

The claims are further restricted as follows:

Claims 1-52, 59-61, 76-85 of Group 1 comprise specifically named mutants of InsP3R and one mutant must be elected. Each of the mutants is distinct from each other as each comprises a different structure and biological activity.

Claims 53 of Group 2 comprises specifically named nucleic acids that encode InsP3R mutants and one mutant must be elected. Each of the mutants is distinct from each other as each comprises a different structure and biological activity.

. Claim 68 of Group 3, claim 73 of Group 4, claims 74 of Invention 5, claim 75 of Invention 6, claim 86 of Group 7, claim 88 of Group 8, and claim 89 of Group 9 comprise cells comprising specifically named nucleic acid sequences that encode Insp3R mutants and one mutant must be elected. Each of the mutants is distinct from each other as each comprises a different structure and biological activity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Michael Pak/

Primary Examiner, Art Unit 1646